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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,441	12/08/2003	Rajeeva Singh	A8689	3309

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2100 Pennsylvania Avenue, N. W.
Washington, DC 20037

EXAMINER	
DUFFY, BRADLEY	
ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
12/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/729,441	SINGH ET AL.	
	Examiner	Art Unit	
	BRADLEY DUFFY	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14-18,22,26-38,41,42,44-60,62 and 63* is/are pending in the application.

4a) Of the above claim(s) *28,29,35,36 and 52-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,14-18,22,26,27,30-34,37,38,41,42,44-51,59,60,62 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 16, 2010, has been entered.

2. The amendment filed February 16, 2010, is acknowledged and has been entered. Claims 11, 14-18, 22, 26-37, 41-42, 45, 59-60 and 62-63 have been amended. Claims 8, 19-21, 24, 25, 39, 40, 43, 61 and 64-72 have been canceled.

3. The amendment filed August 6, 2010, is acknowledged and has been entered. Claims 37, 59 and 60 have been amended.

4. Claims 11, 14-18, 22, 26-38, 41-42, 44-60 and 62-63 are pending in the application.

5. Claims 28, 29, 35, 36 and 52-58 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

6. Claims 11, 14-18, 22, 26, 27, 30-34, 37, 38, 41-42, 44-51, 59, 60 and 62-63 are under examination.

Grounds of Objection and Rejection Withdrawn

7. Unless specifically reiterated below, Applicant's amendment and/or arguments filed February 16, 2010, and/or August 6, 2010, have obviated or rendered moot the grounds of objection and rejection set forth in the previous Office action mailed June 16, 2009.

Grounds of Objection Maintained

Specification

8. The objection to the amendment filed April 16, 2007 under 35 U.S.C. 132(a) because it introduces new matter into the disclosure, is maintained. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention, is maintained. The added material which is not supported by the original disclosure is as follows: the paragraphs added after paragraph 92 from the DeVita et al reference that occurs on pages 2-9 of the amendment.

In the response filed February 16, 2010, Applicant has traversed this objection reiterating the arguments of record and further submitting that the claim amendments overcome the objection.

In response, the previous arguments were not found persuasive for the reason of record as set forth in the office action mailed June 16, 2009. Furthermore, the claim amendments do not overcome the objection because the objection has been made because the specification contains new matter, and this new matter has not been canceled from the specification.

Thus, after a careful and full consideration of Applicant's arguments, it is maintained that the specification amendment adds new mater to the disclosure.

Applicant is invited to provide appropriate rebuttal or cancel the new matter in the reply to this Office Action.

Claims

9. The objection to claims 30, 31 and 34, as being drawn in the alternative to the non-elected invention of Group III, is maintained. Applicant has requested rejoinder of the non-elected claims of Group III, upon allowance of product claims in the response to the restriction requirement filed September 9, 2006. Rejoinder of the non-elected claims of Group III will be considered once all product claims are found allowable. See MPEP 821.04 which states "The propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder".

Grounds of Rejection Maintained

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. The rejection of claims 17, 30, and 32-34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a NEW MATTER rejection.

Starting at page 15 of the response filed February 16, 2010, Applicant has traversed this ground of rejection.

In the response, Applicant has traversed this rejection for the reasons of record and then submits that the claim amendments have overcome the rejection.

In response, the previous arguments were not found persuasive for the reason of record as set forth in the office action mailed June 16, 2009. Furthermore, the claim amendments do not overcome the rejection because claim 17, 30, 32 and 33 all recite pamidronate which as set forth previously is considered NEW MATTER. Furthermore, claim 32 still recites thalidomide and claims 32 and 34 still recite carmustine which as set forth previously are considered NEW MATTER.

Thus, after a careful and full consideration of Applicant's arguments, the specification lacks information to lead one of skill in the art to understand that the applicant had possession of the claimed invention at the time the instant application was filed. Therefore, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed and this rejection is maintained.

Otherwise this issue might be resolved if Applicant were to point to other disclosures in the specification, including the claims, as originally filed, which are believed to provide the necessary written support for the language of the instant claims.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. The rejection of claims 11, 14-18, 22, 26, 27, 30-34, 37, 38, 41-42, 44, 46-51, 59, 60 and 62-63 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of US Patent 7,538,195 in view of Teicher et al, is maintained essentially for the reasons of record, as explained in the Office action mailed October 18, 2006.

In the responses filed February 16, 2010, and August 6, 2010, Applicant has traversed this ground of rejection arguing on February 16, 2010, that “[t]he subject matter of the present application is patentably distinct from the subject matter recited in the claims of the '195 Patent. The Office failed to appreciate Applicants' teachings, "the combined administration of EM164 antibody with taxol was significantly more inhibitory to the growth and survival of non-small cell lung cancer Calu6 cells than was taxol alone. Similarly, the combination of EM164 antibody with camptothecin was significantly more inhibitory than camptothecin alone toward the growth and survival of colon cancer HT29 cells. Because EM164 antibody alone was not expected to be as toxic to cells as organic chemotoxic drugs, the synergism between the predominantly cytostatic effect of EM 164 antibody and the cytotoxic effect of the chemotoxic drug may be highly efficacious in combination cancer therapies in clinical settings." See, e.g., paragraph

145, specification". Then the response filed August 6, 2010, reiterates that synergy is achieved by the present invention.

In response, it is first noted that US application 10/170,390 which issued as US Patent 7,538,195, contains the same disclosure that "the combined administration of EM164 antibody with taxol was significantly more inhibitory to the growth and survival of non-small cell lung cancer Calu6 cells than was taxol alone. Similarly, the combination of EM164 antibody with camptothecin was significantly more inhibitory than camptothecin alone toward the growth and survival of colon cancer HT29 cells. Because EM164 antibody alone was not expected to be as toxic to cells as organic chemotoxic drugs, the synergism between the predominantly cytostatic effect of EM 164 antibody and the cytotoxic effect of the chemotoxic drug may be highly efficacious in combination cancer therapies in clinical settings." (see pages 40 and 41). Furthermore, neither the instant specification nor the specification US Patent 7,538,195 supply any evidence that each and every therapeutic agent as instantly claimed displays synergy and the teachings of Teicher et al related to the agent being bortezomib (PS-341), which is not taught as synergistic in the applications.

Finally, even disregarding the teachings of Teicher it is submitted that the rejection is proper. For example, MPEP § 804.II.B.1 states that when considering obviousness-type double patenting issues, the disclosure of the patent [or copending application] cannot be used as prior art, but "[t]his does not mean one is precluded from all use of the patent disclosure". MPEP § 804.II.B.1 continues, "[t]he specification can always be used as a dictionary to learn the meaning of a term in the patent [or application] claim". Citing *In re Vogel and Vogel*, 164 USPQ 619 (CCPA 1970), MPEP § 804.II.B.1 states, "one must first 'determine how much of the patent [or application] disclosure pertains to the invention claimed in the patent [or application]' because only '[t]his portion of the specification supports the patent claims and may be considered' " and " 'this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, **since only the disclosure of the invention claimed in the patent may be examined**" [emphasis

added]. Consistently, in this instance, the examiner used only that portion of the copending application disclosure that pertains to the claimed invention.

Further addressing *In re Vogel and Vogel*, the Court decided the correctness of the conclusion that a patent claim drawn to a process for packaging "pork" would be obvious over a pending claim drawn to a process for packaging "meat", since although "pork does not read on "meat", "meat" reads literally on "pork". However, the Court further noted "viewing the inventions in reverse order, i.e., as though the broader claims issued first, does not reveal that the narrower (pork) process is in any way unobvious over the broader (meat) invention disclosed and claimed in the instant application" *Id.* at 623. The examiner believes this is because, were the patent claim to broadly recite "meat", although "pork" does not read on "meat" (i.e., a species encompassed by the genus generally does not suffice to describe the genus), the specification states how the claimed process is to be carried out with "pork". The Court indicated that this portion of the specification, stating how the claimed process is to be carried out using pork, supports the patent claims *and may be considered*. *Id.* at 622.

In certain situations, the supporting disclosure may be used to define terms in a claim and to determine whether the invention claimed has been modified in an obvious or unobvious manner. See *Carman Industries, Inc. v. Wahl et al.*, 220 USPQ 481 (CA FC 1983). If modified in an unobvious manner, there is no double patenting issue. In this instance, there can be no mistake that the invention claimed in the instant application is an obvious "variant" of the invention claimed in the patent, because the supporting disclosure of the latter teaches using the antibody in compositions in combination with paclitaxel, i.e. the generic name of the cytotoxic agent present in TAXOL and camptothecin, while the instant claims are generic to compositions comprising any other agent or as set forth in claim 17 e.g., the agent can be paclitaxel.

If the instant claims were drawn instead to an unobvious "variant", or to an invention that might only be gleaned from consideration of portions of the disclosure that do not support the patented claims, such that the consideration would be improper, then there would be no double patenting issue. Because only those portions of the

disclosure that support the patented claims has been considered, and those portions include a description of the “variant” claimed in the instant application, then, double patenting rejection is believed warranted.

Accordingly, the claimed inventions are so substantially similar that for the most part, the claimed subject matter of the patent anticipates the claimed subject matter of the instant application and any minor differences in the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the patent.

Thus, after a careful and full consideration of Applicant’s arguments, it is for these reasons that the nonstatutory obviousness-type double patenting is maintained.

14. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

15. The rejection of claim 45 under 35 U.S.C. 101, as claiming the same invention as that of claim 8 of US Patent 7,538,195, is maintained.

In the responses filed February 16, 2010, and August 6, 2010, Applicant has traversed this ground of rejection arguing on February 16, 2010, that “[t]he subject matter of the present application is patentably distinct from the subject matter recited in the claims of the '195 Patent. The Office failed to appreciate Applicants' teachings, "the

combined administration of EM164 antibody with taxol was significantly more inhibitory to the growth and survival of non-small cell lung cancer Calu6 cells than was taxol alone. Similarly, the combination of EM164 antibody with camptothecin was significantly more inhibitory than camptothecin alone toward the growth and survival of colon cancer HT29 cells. Because EM164 antibody alone was not expected to be as toxic to cells as organic chemotoxic drugs, the synergism between the predominantly cytostatic effect of EM 164 antibody and the cytotoxic effect of the chemotoxic drug may be highly efficacious in combination cancer therapies in clinical settings." See, e.g., paragraph 145, specification". Then the response filed August 6, 2010, reiterates that synergy is achieved by the present invention.

In response, as set forth in the previous action, claim 45 does not require **any** therapeutic agent. Therefore, once again, since the sequences are 100% identical the claims are drawn to compositions of identical scope.

Thus, after a careful and full consideration of Applicant's arguments, the rejection of Claim 45 under 35 U.S.C. 101 is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

16. Claims 47 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a NEW MATTER rejection.

With respect to claim 47 which was newly added December 12, 2008, it appears that the response has introduced NEW MATTER into the claims. In this case claim 47 newly recites cytotoxic agents termed "a small drug", "a prodrug" and "a taxoid". While the response points out where support for the newly added second agents could be found in the originally filed disclosure, it was not found persuasive.

Applicant submits in the response filed December 12, 2008, that support for the new claims occurs “in the claims as filed, throughout the specification including the Sequence Listing and Figures 24-27”.

In response, after considering the claims as filed, the specification as filed and text searching the specification for the terms "small drug”, “prodrug” and “taxoid” support for these agents could not be found in the specification as filed.

Then with respect to claim 60, in the response filed August 6, 2010, the claim was amended to “a humanized or resurfaced antibody EM164 produced by ATCC deposit number PTA-4457”.

In this case, Applicant has not indicated where support occurs in the specification for this newly added limitation.

MPEP § 2163 states, “when filing an amendment an applicant should show support in the original disclosure for new or amended claims”. See M.P.E.P. § 714.02 and § 2163.06. Nevertheless, as M.P.E.P. § 2163 further states: “The examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims. See *Wertheim*, 541 F.2d at 263, 191 USPQ at 97”.

After reviewing the specification, it does not appear that the specification, including the claims, as originally filed, provide adequate support for these claims.

At page 69 the specification teaches that the hybridoma deposited as ATCC accession number PTA-4457 makes ***murine*** EM164 antibody, and the specification does not appear to support that the hybridoma additionally produces a humanized or resurfaced antibody EM164.

Therefore, given the apparent difference in the breadth of the claims and that of the pertinent disclosures it is submitted that this clearly illustrates that such amendments have in fact introduced new concepts, thereby violating the written description requirement set forth under 35 U.S.C. §112, first paragraph.

Otherwise this issue might be resolved if Applicant were to point to other disclosures in the specification, including the claims, as originally filed, which are

believed to provide the necessary written support for the language of the instant claims.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30 PM, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
December 16, 2010